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Prevention of early atopic dermatitis by an infant formula supplemented with immunoactive prebiotics in low atopy risk infants

Background: Oligosaccharides (OS) may alter postnatal immune development by influencing the constitution of gastrointestinal bacterial flora. Previous data in infants at risk for development of atopy demonstrate that neutral prebiotic OS (short chain galacto-OS and long chain fructo-OS, ratio 9:1, IMMUNOFORTIS®) mimicking functionally the OS in breast milk reduce the incidence of atopic dermatitis (AD). The aim of this study was to assess the effect of immunologically active OS-supplemented formula feeding on the incidence of early AD in infants at low risk for developing atopy.

Methods: In this randomised controlled double blind European multi-centre trial (7 centres in 5 countries) 1187 healthy term infants without family history of atopy were recruited (including a breastfed reference group). 1130 infants remained in the full analysis set for the intention-to-treat analysis (new prebiotic group: 414; control: 416, breastfeeding reference: 300). Infants were randomized to receive either infant formula supplemented with a mixture of immune-modulating neutral and acidic OS (ratio 85:15, 8g/L formula; (prebiotic) or infant formula without OS-supplementation (control). Infants exclusively breast-fed for 8 weeks or longer served as reference. AD was diagnosed according to the criteria recommended by the European Task Force on Atopic Dermatitis. Fisher's exact test (two-sided) was used for comparison of cumulative incidences, two-sided Mantel-Haenszel logrank test for analysis of first occurrence of AD.

Results: The cumulative incidence of AD at age 16 weeks was 3.6%, 4.8%, and 1.3%, at 24 weeks 4.6%, 7.7%, and 3.3% in the new prebiotic, control and reference group, respectively. At 52 weeks, the cumulative AD incidence was significantly lower in the new prebiotic group (5.6%) than in the control group (9.4 %; P=0.0469), but similar to the reference group (7.0%; n.s.). AD occurred significantly earlier in the control group than in the new prebiotic group (P=0.0411).

Conclusion: This randomised controlled double-blind European multi-centre trial indicates a preventive effect of specific immunoactive OS-supplemented formula feeding on the incidence of early AD in infants at low risk for atopy development. The finding is particularly intriguing since most children afflicted from AD in a general population come from low atopy risk strata. Future research should also aim at longer-term effects of this strategy to prevent AD.